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Supreme Court of the United States

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APOTEX, INC.,

*Petitioner,*

*v.*

JANSSEN PHARMACEUTICA, N.V.  
and JANSSEN, L.P.,

*Respondents.*

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ON PETITION FOR A WRIT OF CERTIORARI TO THE  
UNITED STATES COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT

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**PETITION FOR A WRIT OF CERTIORARI**

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January 27, 2009

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## QUESTION PRESENTED

This is one of many suits brought by generic pharmaceutical manufacturers seeking a declaratory judgment that an equivalent generic drug product will not infringe a patent held by the brand-name manufacturer. Indeed, petitioner Apotex Inc. has filed numerous such suits, only to suffer significant injury when they were dismissed based upon the misapplication of controlling precedent from this Court. These dismissals continue despite this Court's decision in *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764 (2007).

The Question Presented is whether such a suit states a justiciable controversy when, as in this case, the failure to secure a court judgment prohibits the federal government from approving the generic equivalent and the prospect of massive patent liability deters the generic manufacturer from entering the marketplace.

## **LIST OF PARTIES**

All parties in the proceedings below are listed in the caption to this Petition.

### **RULE 29.6 CORPORATE DISCLOSURE STATEMENT**

The parent company of Apotex Inc. is Apotex Pharmaceutical Holdings, Inc. There is no publicly-held corporation that owns 10% or more of Apotex Inc.

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## OPINIONS BELOW

The decision of the United States Court of Appeals for the Federal Circuit (App. 1a-22a)<sup>1</sup> for which review by this Court is sought is available at No. 2008-1062, 540 F.3d 1353 (Fed. Cir. 2008). The decision of the United States District Court for the District of New Jersey that was reviewed by the Federal Circuit (App. 23a-30a) is reported at No. 06-1020 (DMC), 2007 WL 3014702 (D.N.J. Oct. 11, 2007).

## JURISDICTION

The Federal Circuit's judgment for which review by this Court is sought was entered on September 4, 2008. The Federal Circuit entered an Order denying Apotex's combined petition for panel rehearing and for rehearing *en banc* on October 29, 2008. (See App. 31a-32a). This Court has jurisdiction to review the judgment of the Federal Circuit under 28 U.S.C. § 1254(1).

## CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

U.S. Constitution, art. III, § 2, cl. 1 provides in pertinent part:

The judicial Power shall extend to all Cases, in Law and Equity, arising under this Constitution, the Laws of the United States, and Treaties made, or which shall be made, under their Authority; . . . .

(App. 33a.)

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<sup>1</sup> References to "App. \_\_\_\_" are to the Appendix attached hereto, as required under Supreme Court Rule 14.1(i).

21 U.S.C.A. § 355(j)(5)(C)(i)(II) (West Supp. 2005) provides:

**(C) Civil action to obtain patent certainty.-**

**(i) Declaratory judgment absent infringement action.-**

\* \* \*

**(II) Filing of civil action.-** If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval . . . .

(App. 34a-38a.)

35 U.S.C.A. § 271(e)(5) (West Supp. 2005) provides:

Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of

which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

(App. 39a.)

### STATEMENT OF THE CASE

1. This case involves federal court subject matter jurisdiction, not chemistry. This case involves the tension between open and free competition in the marketplace versus the stranglehold over competition by patent law and law of the U.S. Food and Drug Administration ("FDA"). This case involves the use of a Declaratory Judgment to pry open the competitive bottleneck. This petition arises from a patent dispute between respondents Janssen Pharmaceutica, N.V. and Janssen, L.P. (collectively, "Janssen") and petitioner Apotex. Janssen has patents relating to risperidone oral solution, which it sells under the brand-name Risperdal®. Risperdal® is indicated for the treatment of certain mental disorders, and has generated billions in sales. Apotex developed a generic version of Risperdal® oral solution and seeks approval from FDA to market that generic product pursuant to the Hatch-Waxman Act, which amended the Federal Food, Drug, and Cosmetic Act.

Relevant here, to protect its monopoly, Janssen listed with FDA three patents in connection with Risperdal® oral solution: U.S. Patent Nos. 4,804,663 ("the '663 patent"),



5,453,425 (“the ‘425 patent”) and 5,616,587 (“the ‘587 patent”) (collectively, “Janssen’s Orange Book Patents”).<sup>2</sup> The ‘663 patent expired on June 29, 2008, while the ‘425 and ‘587 patents do not expire until January 11, 2015.<sup>3</sup> Apotex followed the statutory procedure for launching its generic equivalent to Risperdal<sup>®</sup> oral solution by submitting to FDA an abbreviated new drug application (“ANDA”) demonstrating that Apotex’s generic product is “bioequivalent” to Janssen’s branded Risperdal<sup>®</sup> oral solution. Apotex sought FDA approval for its ANDA product prior to expiration of all three of Janssen’s Orange Book Patents, representing that those patents are invalid, unenforceable, or would not be infringed by Apotex’s ANDA product. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a so-called “paragraph IV certification”).

Apotex’s paragraph IV certification to Janssen’s Orange Book Patents constitutes a statutory act of patent infringement sufficient to vest the federal courts with subject matter jurisdiction to resolve patent disputes prior to Apotex’s actual marketing of its ANDA product. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2)(A) (making

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<sup>2</sup> Federal law requires Janssen to submit to FDA the number and expiration date of any patent that claims the “drug” or a “method of using [the] drug” (here, risperidone) and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. §§ 355(b)(1), (c)(2); 21 C.F.R. §§ 314.53(b), (c)(2). Upon approval of the branded drug, FDA publishes this patent information in “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly known as the “Orange Book.” *See* 21 U.S.C. § 355(j)(7)(A)(iii).

<sup>3</sup> The ‘663 patent actually expired on December 29, 2007, but Janssen obtained a 6-month regulatory exclusivity period attaching to that patent. *See* 21 U.S.C. § 355a. That period ended on June 29, 2008. Janssen also obtained a 6-month regulatory exclusivity period for the ‘425 and ‘587 patents, which otherwise would expire on July 11, 2014.

the submission of a paragraph IV certification a statutory act of patent infringement); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990).

While Janssen promptly sued Apotex for alleged infringement of the earliest-expiring '663 patent, Janssen intentionally refrained from bringing an immediate suit against Apotex on the later-expiring '425 and '587 patents. Janssen did so precisely because the lack of a court decision on these two patents would indefinitely delay generic competition for Janssen's branded Risperdal<sup>®</sup> product. Indeed, because Apotex did not file the first ANDA challenging Janssen's Orange Book Patents, Janssen's strategic decision to hold back suit on the '425 and '587 patents delays competition in two separate and distinct ways:

First, the failure to resolve the patent controversy created a substantial cloud of uncertainty over Apotex's ability to enter the marketplace because Apotex faced potentially crippling patent liability if it launched its generic risperidone product, but ultimately lost its patent challenge.

Second, and more importantly here, the failure to secure a court judgment of non-infringement or invalidity precludes Apotex *as a matter of law* from selling its drug until *at least* 180 days after the expiration of the '663 patent. Indeed, Apotex's approval already has been delayed far longer than 180 days, and is potentially indefinite.<sup>4</sup> More

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<sup>4</sup> See SHASHANK UPADHYE, *GENERIC PHARMACEUTICAL PATENT AND FDA LAW* § 13:8 (Thomson West 2008), available on Westlaw database: GENPHARMA ("Because of the law change that occurred in December 2003 with the MMA entering into effect, it is worthwhile to revisit briefly the law of triggers of that time. In the pre-MMA world, there were two triggers of the clock: (i) the commercial marketing trigger; and (ii) the court decision trigger. An entire cottage industry of litigation erupted over when is marketing of a product a commercial marketing and, certainly, what is a court decision that triggers the exclusivity. As to the commercial marketing trigger, essentially when the ANDA applicant

specifically, federal law grants the first generic manufacturer to file an ANDA containing a paragraph IV certification (the so-called "first-filer") the right to sell its ANDA product as the only generic product for 180 days, measured from the earlier to two statutory "triggering events." *See* 21 U.S.C. § 355(j)(5)(B)(iv).<sup>5</sup> If Apotex secures a court decision finding the '425 and '587 patents invalid or not infringed, the 180-day period for those patents would begin to run immediately under the "court decision" trigger. 21 U.S.C.

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began marketing its own ANDA-approved product, then it would trigger its own exclusivity. Because no other later-filed ANDA could be approved until day 181, it makes sense that the commercial marketing trigger could only be of the first-to-file's own ANDA-approved product. The only odd exception is where the generic company markets the brand product but the FDA considers this as a trigger.

As to the court decision trigger, though, litigation erupted on a number of points:

- whether the court decision had to be a decision from the first-to-file's litigation (if any) or could the court decision come from another's case
- whether the court decision had to be from a district court or an appeals court
- whether the court decision had to be a "real" substantive holding that held the patent to be invalid or noninfringed
- whether a procedural determination (e.g., the patentee walks away from the case by dismissing with or without prejudice) triggers the clock
- whether the estoppel effect (or other preclusive effects) qualified as a court decision (e.g., patentee grants a covenant-not-to-sue").

<sup>5</sup> Because the first ANDA for risperidone oral solution containing a paragraph IV certification was submitted before December 8, 2003, the pre-MMA text of § 355(j)(5)(B)(iv) controls. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003 § 1102(b)(1) and (3), Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA"). Because Apotex's counterclaims on the '425 and '587 patents were pending "on or after" enactment of the MMA, Apotex can rely upon the declaratory judgment provisions of that legislation. *See* MMA § 1101(c)(1).

§ 355(j)(5)(B)(iv)(II). Absent such a court decision on the '425 and '587 patents, the first-filer's exclusivity will not begin to run until the first-filer begins commercially marketing its ANDA product under the "commercial marketing" trigger. *Id.* § 355(j)(5)(B)(iv)(I). In this case, the first-filer has had the legal right to begin marketing its generic risperidone oral solution product since June 29, 2008. Had the first-filer done so, Apotex would be on the market by now because Apotex is currently tentatively approved but-for the 180-day exclusivity bottlenecking Apotex's final launch approval. But because the first-filer has been unable to secure FDA approval of its ANDA product (and indeed might never be able to secure such approval), Apotex cannot lawfully obtain approval and begin marketing, severely injuring both Apotex and the public, which continues to pay monopoly prices for Janssen's branded product when an FDA approvable generic version (Apotex's) is ready for immediate marketing. As of today, the first-filer is not yet finally approved despite having filed its ANDA in 2002 and having been approvable (but not approved) since 2006.

Congress enacted a statutory scheme specifically designed to prevent brand-name manufacturers like Janssen from delaying generic market entry with the tactics seen here. Federal law provides that Janssen's submission of the '425 and '587 patents to FDA constitutes a representation that "a claim of patent infringement could reasonably be asserted" based on this patent against a generic competitor. 21 U.S.C. § 355(b)(1). Further, Apotex's filing of its ANDA (with the paragraph IV certification) constituted a statutory act of patent infringement of the '425 and '587 patents. 35 U.S.C. § 271(e)(2)(A). In such circumstances, Congress specifically conferred on the federal courts jurisdiction over a declaratory judgment action by a generic manufacturer, 21 U.S.C. § 355(j)(5)(C)(i)(II), and directed that such suits

should be adjudicated to the fullest "extent consistent with the Constitution," 35 U.S.C. § 271(e)(5).

2. In response to Janssen's infringement suit on the '663 patent, Apotex asserted declaratory judgment counterclaims with respect to all three of Janssen's Orange Book Patents. But in order to improperly maintain its stranglehold over the relevant market, Janssen moved to dismiss Apotex's declaratory judgment counterclaims on the '425 and '587 patents for lack of subject matter jurisdiction. Despite this Court's precedent, under which an actual controversy exists under Article III of the Constitution any time (a) there is an actual or imminent injury-in-fact, (b) that is fairly traceable to the defendant, and (c) is redressible by a favorable decision, the district court nevertheless dismissed Apotex's declaratory judgment counterclaims on the '425 and '587 patents. (App. 23a-30a). The district court did so solely based upon an insufficient and unsolicited covenant not to sue provided by Janssen during the litigation, concluding that "[w]hile there may have been a case or controversy prior to [Janssen] providing the covenant not to sue, no case or controversy exists regarding the '425 and '587 patents, as a result of the covenant not to sue." (App. 26a). The district court's dismissal is materially inconsistent with controlling precedent from this Court, including *MedImmune* because:

- Apotex is suffering, and continues to suffer, actual and continuing injury because, absent a declaratory judgment, (i) the approval of Apotex's non-infringing generic risperidone product is being indefinitely delayed, thus nullifying Apotex's significant investments in research and development, and (ii) Apotex to this day still is unable to launch its generic risperidone product and compete fairly in the

market, despite the expiration of Janssen's basic patent back in June 2008;

- Apotex's injuries result directly from (i) Janssen's decision to obtain and list the '425 and '587 patents in FDA's Orange Book in order to delay generic competition, thus requiring that Apotex address such patents in its ANDA, and (ii) Janssen's refusal to litigate a legitimate dispute regarding such patents solely for the purpose of indefinitely delaying Apotex's approval and maintaining Janssen's monopoly, which refusal continues to delay Apotex's approval just as if Janssen had successfully asserted such patents; and
- Resolving this conflict would not lead to an advisory opinion, where a declaration of non-infringement would allow Apotex to obtain approval of its product and compete fairly in the market.

Indeed, even the Federal Circuit agreed that subject matter jurisdiction existed over Apotex's declaratory judgment counterclaims with respect to the '425 and '587 patents *at the time Apotex filed them*. (App. 14a-15a).

3. The Federal Circuit had exclusive jurisdiction over Apotex's appeal. 28 U.S.C. § 1295(a)(1). Janssen argued that because it gave Apotex an unsolicited covenant not to sue with respect to the '425 and '587 patents, "there is no case or controversy" with respect to Apotex's declaratory judgment counterclaims to these two patents. Janssen's arguments ran contrary to controlling precedent from the Federal Circuit itself, as well as from this Court. In *Caraco Pharmaceutical Laboratories, Ltd. v. Forest Laboratories, Inc.*, 527 F.3d 1278 (Fed. Cir. 2008), which issued after this



Court's decision in *MedImmune* and after Apotex filed its appeal, the Federal Circuit expressly considered whether a covenant not to sue from a brand company to a subsequent ANDA filer (such as Apotex here) divests the federal courts of subject matter jurisdiction. The Federal Circuit in *Caraco* correctly concluded in light of precedent from this Court that, in the Hatch-Waxman context, Article III jurisdiction exists over an ANDA applicant's declaratory judgment claim involving unasserted Orange Book-listed patents, even if the patentee provides a covenant not to sue with respect to such patents, because the generic company had an injury-in-fact sufficient to establish an Article III "case or controversy" based upon being excluded from selling its non-infringing drug product due to the brand company's actions, which delayed FDA approval. *Caraco*, 572 F.3d at 1291-94.

The *Caraco* court's conclusion is mandated by several decisions from this Court, including *MedImmune*, 127 S. Ct. at 771; *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-41 (1937); *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 102-03 (1998); *Bennett v. Spear*, 520 U.S. 154, 167 (1997); *Ne. Fla. Chapter of the Associated Gen. Contractors of Am. v. City of Jacksonville, Florida*, 508 U.S. 656, 664-68 (1993) (finding injury under Article III where plaintiff was precluded by law from competing); *Watt v. Energy Action Educ. Found.*, 454 U.S. 151, 160-61 (1981) (same); *Regents of Univ. of Cal. v. Bakke*, 438 U.S. 265, 281 & 281 n.14 (1978) (finding Article III injury based on university's "decision not to permit [the plaintiff applicant] to compete for all 100 places in the class"); *Clements v. Fashing*, 457 U.S. 957, 962 (1982) (finding Article III injury based on law that created an "obstacle to [plaintiff's] candidacy for higher judicial office" (citations omitted)).

While the Federal Circuit decision appealed here concluded that subject matter jurisdiction existed over Apotex's declaratory counterclaims at the time Apotex filed

them (App. 14a-15a), the court nevertheless impermissibly affirmed the district court's dismissal on those claims (App. 22a). The Federal Circuit refused to apply *Caraco* and the decisions of this Court solely because Apotex stipulated to the validity of the '663 patent – a patent that expired in 2008, nearly seven years before the '425 and '587 patents will expire in 2014.<sup>6</sup> (App. 14a-16a). The Federal Circuit further concluded that any delay in the approval of Apotex's risperidone oral solution ANDA “was too speculative to create an actual controversy to warrant the issuance of a declaratory judgment.”<sup>7</sup> (App. 20a). In other words, the Federal Circuit refused to apply this Court's precedent to find subject matter jurisdiction even though the situation presented here and in *Caraco* admittedly are identical, other than the fact that Apotex recognized the validity of an earlier-expiring patent after the Federal Circuit upheld that patent's validity. The Federal Circuit's ruling cannot lawfully stand. First, under this Court's precedent, that Apotex stipulated to the validity of the earlier-expiring '663 patent has no legal significance with respect to the Article III case or controversy surrounding its declaratory judgment claims to the '425 and '587 patents, which again, do not expire until 2014. Second, Apotex's harm is far from “speculative.” Indeed, it is difficult to envision more real, immediate, and concrete injuries than those which Apotex currently suffers. The '663 patent expired in June 2008, yet Apotex still cannot launch its ANDA product because the

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<sup>6</sup> Apotex stipulated to the validity of the '663 patent only *after* the Federal Circuit found that patent to be valid in litigation involving another generic company. See *Janssen Pharmaceutica N.V. v. Mylan Pharms., Inc.*, 223 Fed. App'x 999, 2007 WL 1428462 (Fed. Cir. May 11, 2007) (unpublished), *aff'g* 456 F. Supp. 2d 644 (D.N.J. 2006).

<sup>7</sup> Apotex's injury continues as the first-filer has yet to launch despite the expiration of the relevant blocking patent in June 2008.



180-day generic exclusivity has not yet started, let alone expired. And there simply is no telling when (if ever) that exclusivity might expire absent a court decision on the '425 and '587 patents.

### **REASONS FOR GRANTING THE WRIT**

The Federal Circuit's holding that manufacturers in Apotex's position are forbidden from maintaining a declaratory judgment action, pursuant to the Federal law enacted for this precise purpose, merits this Court's review. That decision simply cannot be reconciled with this Court's precedents interpreting the case or controversy requirement of Article III, including the Court's recent *MedImmune* decision. The question is, moreover, of indisputable importance not only to the generic pharmaceutical industry, but also to the public, which relies so heavily – particularly in these financially troubled times – on that industry to provide lower-priced, affordable versions of life-saving drugs. Indeed, given the Federal Circuit's continued misapplication of this Court's precedent, it is critical that this Court take up this issue directly in a Hatch-Waxman patent infringement case. Accordingly, this Court should grant certiorari. At the very least, the Court should invite the Solicitor General to file a brief expressing the views of the United States on this vitally important issue because generic drugs are cheaper for the consuming public and for payors, like Health and Human Services.

#### **I. Despite *MedImmune*, The Federal Circuit Continues To Misapply Controlling Precedent From This Court, As It Did In This Case.**

In early 2007, this Court made clear that a declaratory judgment plaintiff need not satisfy the Federal Circuit's judge-made "reason apprehension" test in order for subject matter jurisdiction to exist. *MedImmune*, 127 S. Ct.

at 774 n.11. Indeed, this Court even discussed the Federal Circuit decision upon which Janssen relied in the district court when it sought to dismiss Apotex's claims in this case, *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1333 (Fed. Cir. 2005) ("*Teva*"), when so concluding:

Even if *Altwater* [*v. Freeman*, 319 U.S. 359 (1943)] could be distinguished as an "injunction" case, it would still contradict the Federal Circuit's "reasonable apprehension of suit" test (or, in its evolved form, the "reasonable apprehension of *imminent* suit" test, *Teva Pharm. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1333 (2005)). A licensee who pays royalties under compulsion of an injunction has no more apprehension of imminent harm than a licensee who pays royalties for fear of treble damages and an injunction fatal to his business. The reasonable-apprehension-of-suit test also conflicts with our decisions in *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273, 61 S.Ct. 510, 85 L.Ed. 826 (1941), where jurisdiction obtained even though the collision-victim defendant could not have sued the declaratory-judgment plaintiff-insurer without first obtaining a judgment against the insured; and *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 239, 57 S.Ct. 461, 81 L.Ed. 617 (1937), where jurisdiction obtained even though the very reason the insurer sought declaratory relief was that the insured had given no indication that he would file suit. It is also in tension with *Cardinal Chemical Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 98, 113 S.Ct. 1967, 124 L.Ed.2d 1 (1993), which held that appellate

affirmance of a judgment of noninfringement, eliminating any apprehension of suit, does not moot a declaratory judgment counterclaim of patent invalidity.

*MedImmune*, 127 S. Ct. at 774 n.11. Thus, this Court expressly overruled the reasonable apprehension test.

Moreover, and significantly here, this Court once again confirmed that the only prerequisite to jurisdiction under the Declaratory Judgment Act is an "actual controversy" under Article III, which merely requires: (1) an actual or imminent injury-in-fact, (2) that is fairly traceable to the defendant, and (3) is redressible by a favorable decision. *See id.* at 771; *see also Aetna*, 300 U.S. at 239-41; *Steel Co.*, 523 U.S. at 103-04; *Bennett*, 520 U.S. at 167; *Cardinal Chem.*, 508 U.S. at 95-96.<sup>8</sup> The Federal Circuit's conclusion below that Apotex's stipulation to the validity of the '663 patent somehow rendered its harm "too speculative to create an actual controversy to warrant the issuance of a declaratory judgment" (App. 20a; *see also* App. 14a-15a) runs contrary to this binding precedent.

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<sup>8</sup> A few months later, in another Hatch-Waxman ANDA patent case, the Federal Circuit acknowledged that *MedImmune* overruled the "reasonable apprehension" test. *See Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1338-39 (Fed. Cir. 2007) (hereinafter, "*Novartis*"). As the *Novartis* court went on to hold, the only

question in this [ANDA] case is whether [the generic company] has a justiciable controversy within Article III, which is the only limitation on our jurisdiction under the Declaratory Judgment Act. *See* 28 U.S.C. § 2201. An Article III controversy is found where a plaintiff has demonstrated an injury-in-fact caused by the defendant that can be redressed by the court. *See Steel Co.*, 523 U.S. at 83, 118 S.Ct. 1003.

*Novartis*, 482 F.3d at 1340.

That Apotex stipulated to the validity of the earlier-expiring '663 patent has no legal significance whatsoever with respect to the Article III case or controversy surrounding its declaratory judgment claims to the '425 and '587 patents, and further, the considerable injuries that Apotex continues to suffer based upon its inability to market its generic drug product are far from "speculative." Allowing the Federal Circuit's decision to stand not only would run contrary to this Court's precedent, but also would place generic companies back in the same untenable position that existed under the Federal Circuit's reasonable apprehension test.

In listing the '425 and '587 patents with FDA, Janssen formally took the position that generic competitors were subject to suit for infringement of those patents if they marketed prior to their expiration. Apotex seeks to market its generic product before the '425 and '587 patents expire, and maintains that its product would not infringe those patents or that they are invalid. Apotex currently is injured by virtue of Janssen's conduct, irrespective of Apotex's stipulation to the validity of the now-expired '663 patent.

Janssen's conduct prevented Apotex from entering the marketplace immediately upon expiration of the '663 patent in June 2008, and continues to prevent Apotex's marketing even today, because federal law prohibits FDA from finally approving Apotex's generic product until the 180-day generic exclusivity period expires. But absent a court decision with respect to the '425 and '587 patents, that exclusivity period will not begin to run until the first-filer markets its generic product. Here, however, the first-filer for generic risperidone oral solution has yet to obtain the approval needed to launch its product, and even assuming it can ever obtain such approval, there is no guarantee that it will immediately launch its product. Thus, Apotex's market entry remains blocked indefinitely. No one can reasonably

dispute that Apotex suffers considerable, immediate and ongoing injury given that (i) the approval of its non-infringing generic risperidone product is being delayed, thus nullifying Apotex's significant investments in research and development, and (ii) Apotex, to this day, still is unable to launch its generic risperidone product and compete fairly in the market, despite the expiration of Janssen's basic patent more than seven months ago. Indeed, even the Federal Circuit below conceded that Article III jurisdiction existed over Apotex's declaratory judgment counterclaims with respect to the '425 and '587 patents at the time Apotex filed them. (App. 14a-15a).

The only reason the Federal Circuit refused to find jurisdiction over Apotex's counterclaims to the '425 and '587 patents is because Apotex stipulated to the validity of the '663 patent after the Federal Circuit (in another action) upheld its validity. (App. 14a-16a). But what Apotex did or did not do with respect to a patent that expired nearly seven years before the '425 and '587 patents will expire in 2014 has no bearing on whether an Article III case or controversy exists as to Apotex's declaratory judgment claims to those later-expiring patents. If the '663 patent had never existed and only the '425 and '587 patents were listed in the Orange Book, Apotex would still suffer the same injuries that it does today, and was suffering at the time it brought its declaratory judgment claims -- namely, the inability to promptly bring an admittedly non-infringing product to market and patent uncertainty. And again, the Federal Circuit correctly concluded that jurisdiction existed when Apotex filed its declaratory judgment claims. Apotex's injuries have only increased today, as the approval of its product continues to be delayed indefinitely based upon Janssen's actions.

The fact is that under this Court's precedent, Apotex had the right to enter the generic drug market with its non-infringing product immediately upon expiration of the '663

patent and Apotex's exclusion from the generic drug market by Janssen's actions is a sufficient Article III injury-in-fact. See *Ne. Fla. Chapter*, 508 U.S. at 664-68 (finding injury under Article III where plaintiff was precluded by law from competing); *Watt*, 454 U.S. at 160-61 (same); *Regents*, 438 U.S. at 281 & 281 n.14 (finding Article III injury based on university's "decision not to permit [the plaintiff applicant] to compete for all 100 places in the class"); *Clements*, 457 U.S. at 962 (finding Article III injury based on law that created an "obstacle to [plaintiff's] candidacy for higher judicial office" (citations omitted)).

Notably, the Federal Trade Commission—the independent government agency charged with protecting consumers and policing anticompetitive activities—strongly agrees that parties in Apotex's position satisfy Article III's case or controversy requirement under this Court's precedent: "The controversy is real and immediate, and is between adverse parties, because [Janssen's] conduct creates a bottleneck that just as surely delays [Apotex] from receiving FDA approval to market a product as if [Janssen] had won a preliminary injunction in an infringement suit against [the competitor]." *Teva* FTC Panel Br. at 22-23. "Absent such a decision," every generic competitor "must wait for its approval until [the first-filer] has marketed its product for 180 days . . . . Thus, the only way that [Apotex] can advance the date of the approval of its product is through this litigation. Absent this action, [Apotex] suffers an injury-in-fact from the lost opportunity to bring its product to market during the 180 days." *Id.* at 21-22.



## II. The Federal Circuit's Decision Seriously Undermines Congress's Determination To Enhance Generic Pharmaceutical Competition For The Benefit Of The American Public.

The Federal Circuit's error is all the more grave because it threatens to nullify an entire statutory scheme. Congress enacted the declaratory judgment provisions invoked by Apotex in this case for the express purpose of permitting suits, such as Apotex's, to go forward in order to ensure that the American public has prompt access to essential, less-expensive generic medicines.

Before the 1984 Hatch-Waxman Act, a generic company had to wait until the patent protecting a drug product expired before it could even begin the lengthy process of preparing its application for submission to FDA. And because such testing can, and often does, take years, the brand company continued to monopolize that particular drug market years *after* patent expiration as the generic company worked to complete the necessary tests and waited for FDA approval. This unintended period of extended market exclusivity often was referred to as a "*de facto*" patent term extension. See generally SHASHANK UPADHYE, *GENERIC PHARMACEUTICAL PATENT AND FDA LAW* § 9:2 (Thomson West 2008), *available on* Westlaw database: GENPHARMA (discussing the genesis of the Hatch-Waxman Act and eliminating the *de facto* extension).

In 1984 and again in 2003, Congress amended the statute in numerous respects in order to speed generic competition. Congress provided that: (a) a brand-name manufacturer's submission of a patent to FDA constitutes a representation that "a claim of patent infringement could reasonably be asserted," 21 U.S.C. § 355(b)(1); (b) the filing of an ANDA claiming patent non-infringement or invalidity constitutes a statutory act of patent infringement, 35 U.S.C. § 271(e)(2)(A); (c) federal courts have jurisdiction over such

a declaratory judgment action by a generic manufacturer, 21 U.S.C. § 355(j)(5)(C)(i)(II); 35 U.S.C. § 271(e)(5); and (d) such suits should be adjudicated to the fullest “extent consistent with the Constitution,” 35 U.S.C. § 271(e)(5).<sup>9</sup>

Through this scheme, Congress sought to “enable the judicial adjudication upon which the ANDA . . . scheme[] depend[s].” *Eli Lilly*, 496 U.S. at 678. Congress correctly recognized the substantial national interest in getting “generic drugs into the hands of patients at reasonable prices—fast,” *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991), and specifically sought to ensure that “courts will find jurisdiction, where appropriate, to prevent an improper effort to delay infringement litigation between generic drug manufacturers and pioneer drug companies,” H.R. CONF. REP. NO. 108-391, at 836 (2003). To effectuate that goal, Congress enacted the declaratory judgment provisions to “ensure that the 180-day exclusivity period enjoyed by the first generic to challenge a patent cannot be used as a bottleneck to prevent additional generic competition.” 149 CONG. REC. S15,746 (Nov. 24, 2003).

The Federal Circuit’s continued refusal to correctly apply this Court’s precedent for determining the existence of an Article III case or controversy accordingly will have far-reaching, negative consequences for generic pharmaceutical companies and the American public that depends upon generic companies like Apotex to bring more affordable drugs to market quickly. Because the Federal Circuit has

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<sup>9</sup> Congress also specifically overturned the Federal Circuit’s holding that any company that manufactured or used a patented drug while compiling the data necessary to complete an application for FDA approval of a generic drug could be sued for infringement, see *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 861-63 (Fed. Cir. 1984), superseded by 35 U.S.C. § 271(e)(1), which was a principal source of brand name manufacturers’ *de facto* patent term extensions.



exclusive jurisdiction over patent disputes, the ruling below governs every attempt in the nation by generic pharmaceutical companies to resolve patent disputes with brand manufacturers. The decision below provides a roadmap for brand manufacturers to preclude litigation of all such disputes. The Federal Circuit's ruling encourages brand companies to delay infringement litigation, and as a result, the market entry of much-needed affordable generic drugs. *Teva Pharms. USA, Inc. v. Pfizer Inc.*, 405 F.3d 990, 994-95 (Fed. Cir. 2005) (Gajarsa, J., dissenting) ("No incumbent will ever make the threat [of litigation], if it can simply ride out the term in the listed patent.").

Thus, the Federal Circuit's decision, by misapplying this Court's precedent, cripples generic competition by leaving generic companies like Apotex under a debilitating cloud of patent uncertainty and outrightly precludes marketing for a substantial period. Consequently, it seriously undermines Congressional efforts to accelerate the introduction of generic drugs and thereby ameliorate the staggering cost of prescription drugs in the United States.

Brand-name manufacturers routinely employ the tactics used by Janssen in this case to delay competition. A perfect example is Pfizer Inc.'s conduct with respect to the drug Accupril<sup>®</sup>, for which Apotex also submitted an ANDA. Pfizer did not assert all Orange Book patents against generic companies seeking immediate FDA approval. Apotex filed a declaratory judgment action in an effort to obtain patent certainty with respect to its own generic equivalent. A district court dismissed the suit, however, for lack of a case or controversy because Pfizer itself refused to file suit. See *TorPharm, Inc. v. Pfizer Inc.*, No. 03-990-SLR, 2004 WL 1465756 (D. Del. June 28, 2004). But when another generic competitor (Ranbaxy) entered the market, exposing itself to massive damages, Pfizer promptly filed suit. See *Pfizer Inc. v. Teva Pharms. USA, Inc.*, Case No. 2:05-cv-00620-DRD-

MAS (D.N.J.). While several other companies obtained FDA approval to begin marketing their own generic Accupril<sup>®</sup> products, the threat of litigation significantly delayed generic entry, particularly after Pfizer obtained a preliminary injunction preventing Ranbaxy's continued marketing.

Another example involves Apotex and its attempt to promptly market a generic version of Pfizer's Zoloft<sup>®</sup>. In order to delay generic competition, Pfizer refused to sue generic companies, including Apotex, with respect to a Pfizer Orange Book patent. There, too, Apotex filed a declaratory judgment action in an effort to obtain patent certainty with respect to its own generic equivalent. A district court dismissed the suit for lack of a case or controversy, and the Federal Circuit affirmed. *See Apotex, Inc. v. Pfizer Inc.*, 385 F. Supp. 2d 187 (S.D.N.Y. 2005), *aff'd*, No. 05-1199, 2005 WL 3457408 (Fed. Cir. Dec. 12, 2005). And this Court denied Apotex's certiorari petition after the relevant patent expired. *See Apotex, Inc. v. Pfizer Inc.*, No. 05-1006. Indeed, this Court did so despite Apotex's insistence that this same situation would repeat itself again and again, *including with respect to Apotex's generic Risperdal<sup>®</sup> product*, the very generic product at issue here now. (See No. 05-1006, Declaration of Dr. Bernard C. Sherman ¶¶ 12-13, submitted Sept. 19, 2006, in connection with the Supplemental Brief for Petitioners).

Thus, at least two things are clear: (1) brand companies like Janssen have, in effect, created a new "*de facto*" exclusivity period in direct contravention of Congress's express intent; and (2) they will continue to use this "*de facto*" exclusivity period to harm generic companies like Apotex and the public unless this Court intervenes. The consequences for the American public are, in fact, substantial.

As the Federal Trade Commission advised the Federal Circuit, "declaratory judgment actions serve an important role because the [FTC's] Generic Drug Study showed that no generic applicant entered the market prior to a district court decision addressing the patents that, at the time of its application, were listed in the Orange Book." *Teva* FTC Panel Br. at 8 n.9 (emphasis added).

The high costs of brand-name prescriptions are a significant barrier in most cases to proper medical treatment for many Americans, particularly the elderly. See AARP, *Prescription Drug Costs and the Role of Generic Drugs: Public Opinion Among Americans Aged 45 and Older* at 2 (Oct. 1, 2002) ("[N]early one in four Americans 45 and older (24%) reported not being able to afford a prescription drug because no generic version was available."). Because generic drugs are sold for a fraction of the prices of their brand-name counterparts, access to generic pharmaceuticals is "perhaps the single most important route to lower personal and national drug costs during the next decade." Steven Findlay, *Easy Way to Cut Costs of Drugs: Generics*, USA TODAY, May 13, 2004, at 23A,.

As the FDA Commissioner has explained, generic drugs "are an increasingly important way to provide the American people with safe, effective and affordable medical treatment." U.S. Food and Drug Administration, *FDA Announces Measures to Improve Generic Drug Access* (Mar. 2, 2004), available at [www.fda.gov/bbs/topics/NEWS/2004/NEW01030.html](http://www.fda.gov/bbs/topics/NEWS/2004/NEW01030.html); see also National Institute for Health Care Management, *A Primer: Generic Drugs, Patents, and the Pharmaceutical Marketplace* 19 (June 2002) (suggesting that the "advent" of generic anti-depressant drugs "may help rectify" "a persistent under-diagnosis and under-treatment of depression in the U.S."). The cost savings resulting from the availability of generic drugs is inescapable. Indeed, the

substitution of generic drugs for brand-name drugs results in billions of dollars in savings each year, without compromising safety or health.<sup>10</sup> Jennifer S. Haas, *et al.*, *Potential Savings from Substituting Generic Drugs for Brand-Name Drugs: Medical Expenditure Panel Survey, 1997-2000*, 142 ANNALS OF INTERNAL MEDICINE 891, 895 (June 7, 2005) (indicating that “[b]road dispensing of generic products would achieve savings without compromising safety,” because “[g]eneric drugs are believed to provide therapeutic effects similar to those of their brand-name alternatives”); U.S. Food and Drug Administration, *FDA White Paper: New FDA Initiative on “Improving Access to Generic Drugs”* (June 12, 2003), available at <http://www.fda.gov/oc/initiatives/generics/whitepaper.html> (recognizing that “Americans need generic drugs more than ever” and “[b]ringing low-cost generic drug alternatives to consumers more quickly can significantly reduce overall health care costs, and increase access to life saving medicines that are just as safe and effective as their brand-name counterparts”).

Thus, the decision of the Federal Circuit will have far-reaching negative effects on the American public, as it inevitably and unnecessarily delays access to these lower-cost generic drugs.

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<sup>10</sup> A study published in the ANNALS OF INTERNAL MEDICINE, concluded that “broad generic substitution of outpatient prescription drugs could save approximately \$8.8 billion, or approximately 11% of drug expenditures for adults . . . in the United States each year.” Jennifer S. Haas, *et al.*, *Potential Savings from Substituting Generic Drugs for Brand-Name Drugs: Medical Expenditure Panel Survey, 1997-2000*, 142 ANNALS OF INTERNAL MEDICINE 891, 894 (June 7, 2005); see also Food and Drug Administration, *FDA White Paper: New FDA Initiative on “Improving Access to Generic Drugs”* (June 12, 2003), available at <http://www.fda.gov/oc/initiatives/generics/whitepaper.html> (reporting that the average price of a brand-name drug is \$72, compared with \$17 for its generic counterpart).

## CONCLUSION

The petition for certiorari should be granted. Alternatively, the Court should call for the views of the Solicitor General.

Respectfully submitted,

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January 27, 2009

## **APPENDIX**

**APPENDIX A — OPINION OF THE UNITED  
STATES COURT OF APPEALS FOR THE FEDERAL  
CIRCUIT DECIDED SEPTEMBER 4, 2008**

**UNITED STATES COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT**

No. 2008-1062

JANSSEN PHARMACEUTICA, N.V.  
and JANSSEN, L.P.,

Plaintiffs-Appellees,

v.

APOTEX, INC.,

Defendant-Appellant.

Appeal from the United States District Court for the  
District of New Jersey in case no. 06-CV-1020, Judge  
Dennis M. Cavanaugh.

DECIDED: September 4, 2008

Before MICHEL, *Chief Judge*, RADER and MOORE,  
*Circuit Judges*.

MOORE, *Circuit Judge*.

Defendant-Appellant Apotex, Inc. (Apotex) appeals  
the order of the United States District Court for the  
District of New Jersey dismissing its declaratory



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judgment action for noninfringement against Plaintiffs-Appellees Janssen Pharmaceutica, N.V. and Janssen, L.P. (collectively Janssen). We affirm.

**BACKGROUND****I.**

This case arises under the Hatch-Waxman Act (Act),<sup>1</sup> which governs the Food and Drug Administration's (FDA) approval of new and generic drugs. The goal of the Act is to better balance two competing interests in the pharmaceutical industry: "(1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed.Cir.2002).

Under the Act, a pioneering or brand name drug company seeking to manufacture a new drug must prepare, file, and have approved a new drug application (NDA) with the FDA. 21 U.S.C. § 355(a), (b). As part of its NDA, the applicant must submit information regarding the new drug's safety and efficacy obtained from clinical trials. 21 U.S.C. § 355(b)(1). The applicant

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1. The Hatch-Waxman Act is the name commonly used to refer to the Drug Price Competition and Patent Term Restoration Act of 1984, Pub.L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360(cc) (2000), 35 U.S.C. §§ 156, 271, 282 (2000)), as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L. No. 108-173, 117 Stat.2066 (2003).



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must also identify all patents that "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug," 21 U.S.C. § 355(b)(1), (c)(2). The FDA publishes a list of those patents in the "Orange Book." Drugs approved by the FDA are known as "listed drugs." 21 U.S.C. § 355(j)(2)(A)(i).

To encourage the development of generic versions of listed drugs, the Act created an expedited approval process known as an Abbreviated New Drug Application (ANDA). 21 U.S.C. § 355(j). Generic drug companies are not required to conduct their own independent clinical trials to prove safety and efficacy, but can instead rely on the research of the pioneer pharmaceutical companies. 21 U.S.C. § 355(j)(2)(A)(iv), (j)(8)(B). However, in order to rely on the research of the pioneer pharmaceutical companies, an ANDA applicant is required to show bioequivalence of its generic drug to the NDA drug. 21 U.S.C. § 355(j)(2)(A)(iv), (j)(8)(B). The ANDA applicant must also include a certification to each patent listed in the Orange Book covering the listed drug that either (I) no patent information has been filed with the FDA; (II) the patent has expired; (III) the patent will expire on a particular date and approval of the ANDA should be deferred until expiration; or (IV) in the opinion of the ANDA applicant, the patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug. 21 U.S.C. § 355(j)(2)(A)(vii). These options are respectively referred to as Paragraph I, II, III, and IV Certifications. The timing of ANDA approval is tied to the type of

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certification contained in the ANDA. For Paragraph IV ANDAs, the timing of approval depends upon two events: (1) whether the pioneer drug company brings an infringement action within 45 days of learning of the Paragraph IV ANDA filing, and (2) whether the company seeking approval was the first one to file an ANDA containing a Paragraph IV Certification to a listed patent (hereinafter first Paragraph IV ANDA filer).

In order to bring about early resolution of patent disputes between generics and pioneering drug companies, the Act provides that the filing of a Paragraph IV Certification is an act of patent infringement. 35 U.S.C. § 271(e)(2)(A); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678, 110 S.Ct. 2683, 110 L.Ed.2d 605 (1990). The ANDA filer must provide notice to the patentee and NDA holder of the factual and legal bases for the Paragraph IV Certification. 21 U.S.C. § 355(j)(2)(B). Upon such notice, the patentee and NDA holder have the option of suing on all, some, or none of the patents included in the Paragraph IV Certification. If the patentee or NDA holder does not bring suit within 45 days of receiving notice, the FDA may issue final approval of the ANDA once its approval requirements have been satisfied. 21 U.S.C. § 355(j)(5)(B)(iii). If, however, the brand name company brings suit within 45 days, the FDA may not approve the ANDA for 30 months. 21 U.S.C. § 355(j)(5)(B)(iii). The FDA may approve the ANDA after that period, or earlier if a court has decided the patent(s)-in-suit are invalid or not infringed. 21 U.S.C. § 355(j)(5)(B)(iii).

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As an incentive for generic pharmaceutical companies to challenge suspect Orange Book listed patents, the Hatch-Waxman Act grants the first company to submit a Paragraph IV ANDA a 180-day period of generic marketing exclusivity during which time FDA will not approve a later-filed Paragraph IV ANDA based on the same NDA (hereinafter subsequent Paragraph IV ANDA). 21 U.S.C. § 355(j)(5)(B)(iv); see *Minn. Mining & Mfg. Co. v. Barr Labs., Inc.*, 289 F.3d 775, 778 (Fed.Cir.2002). Significantly, the first Paragraph IV ANDA filer is entitled to the 180-day exclusivity period regardless of whether it establishes that the Orange Book patents are invalid or not infringed by the drug described in its ANDA. All that is required for the first Paragraph IV ANDA filer to receive the 180-day exclusivity period is that it submits a substantially complete ANDA that contains a Paragraph IV Certification. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb).

The start of the 180-day exclusivity period is triggered by the earlier of two events: (1) the first Paragraph IV ANDA filer's commercial marketing of a drug product; or (2) a court decision of noninfringement or invalidity.<sup>2</sup> 21 U.S.C. § 355(j)(5)(B)(iv) (2000). Only the

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2. In 2003, Congress replaced the provisions governing the triggering of the 180-day exclusivity period with a regime in which the 180-day exclusivity period could be forfeited for various reasons, including the failure of the first Paragraph IV ANDA filer to launch its generic product within a certain time period. 21 U.S.C. § 355(j)(5)(D). This amendment was part of

(Cont'd)

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first Paragraph IV ANDA filer can trigger its 180-day exclusivity period via the commercial-marketing trigger. 21 U.S.C. § 355(j)(5)(B)(iv)(I) (2000). However, the subsequent Paragraph IV ANDA filers can trigger the first Paragraph IV ANDA filer's 180-day exclusivity period via a successful court judgment. *Minn. Mining*, 289 F.3d at 780.

On December 8, 2003, the Hatch-Waxman Act was amended by Title XI of the Medicare Prescription Drug, Improvement and Modernization Act of 2003(MMA), Pub.L. No. 108-173, § 1102(a), 117 Stat. 2066, 2457-60. Prior to the MMA, NDA holders employed several methods of delaying the early resolution of patent disputes. *See Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1342 & n. 7 (Fed.Cir.2007). The MMA ameliorates these situations by authorizing a "a civil action" under 28 U.S.C. § 2201 "for a

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(Cont'd)

the Medicare Prescription Drug, Improvement, and Modernization Act of 2003(MMA), Pub.L. No. 108-173, 117 Stat.2066 (2003). However, the MMA contained a grandfather provision specifying that the amendments do not apply to Paragraph IV ANDAs filed before the date of the enactment of the MMA or to subsequent Paragraph IV ANDAs filed after the enactment of the MMA if the first Paragraph IV ANDA was filed prior to enactment of the MMA. *See* MMA § 1102(b). Here, a generic pharmaceutical company, Teva Pharmaceuticals USA, Inc., filed the first Paragraph IV ANDA in 2002, before the December 2003 enactment of the MMA. Thus, the MMA amendments governing the commencement and forfeiture of the 180-day exclusivity period are inapplicable to this case.

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declaratory judgment that the [listed] patent is invalid or will not be infringed by the drug for which the applicant seeks approval . . .” 21 U.S.C. § 355(j)(5)(C)(i)(II). Specifically, the MMA allows a Paragraph IV ANDA filer a right to bring a declaratory judgment action for noninfringement or invalidity of the relevant listed patents against the patentee and NDA holder, if the patentee has not brought an infringement action within the 45-day notice period. 21 U.S.C. § 355(j)(5)(C). Congress extended federal court jurisdiction over these declaratory judgment actions “to the extent consistent with the Constitution.” 35 U.S.C. § 271(e)(5). Therefore, federal courts have jurisdiction over these declaratory judgment actions to the extent that they present an Article III case or controversy. *Caraco Pharm. Labs. v. Forest Labs.*, 527 F.3d 1278, 1285 (Fed.Cir.2008) (citation omitted).

## II.

Janssen holds an approved NDA for its drug Risperdal® Oral Solution. The Orange Book originally listed U.S. Patent Nos. 4,804,663 (‘663 patent), 5,453,425 (‘425 patent) and 5,616,587 (‘587 patent) in connection with this NDA. The 2 663 patent covers the compound risperidone, which is the active compound in the drug Risperdal® Oral Solution. The ‘425 and ‘587 patents cover specific aqueous solutions of risperidone and methods for preparing these solutions. The ‘663 patent expired on December 29, 2007. However, the FDA granted Janssen an additional six months of pediatric exclusivity pursuant to 21 U.S.C. § 355a, making June

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29, 2008 the effective expiration date of the '663 patent.<sup>3</sup> The '425 and '587 patents expire in 2014.

The '663 patent has been the subject of prior litigation. Following a bench trial, it was found to be infringed, valid, and enforceable. On May 11, 2007, this court affirmed the judgment of the district court. *Janssen Pharmaceutica, N.V. v. Mylan Pharm., Inc.*, 456 F.Supp.2d 644, 671 (D.N.J.2006), *aff'd*, 223 Fed.Appx. 999 (Fed.Cir.2007). While Apotex was not a party to that trial, Apotex stipulated to infringement, validity, and enforceability of the '663 patent based on the Federal Circuit opinion. Therefore, this stipulation took effect on May 11, 2007.

Prior to September 2002, Teva Pharmaceuticals USA, Inc. (Teva) filed an ANDA to make a generic version of risperidone oral solution. In filing its ANDA, Teva respected the validity of the '663 patent by filing a Paragraph III Certification on that patent. Teva was the first ANDA applicant to file a Paragraph IV Certification on the '425 and '587 patents. As such, Teva is entitled to 180 days of generic market exclusivity, during which the FDA will not approve a later-filed Paragraph IV ANDA based on the same NDA. Teva's 180-day exclusivity period will begin either the day it begins marketing its drug, or on the date a court determines that the '425 and '587 patents are invalid or

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3. Hereinafter this opinion refers to the expiration of the '663 patent's pediatric exclusivity period as the expiration of the '663 patent.



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not infringed-whichever comes first. 21 U.S.C. § 355(j)(5)(B)(iv) (2000). As Teva filed a Paragraph III Certification with respect to the '663 patent, the FDA will not approve Teva's generic product before the expiration of the '663 patent. Because Janssen did not sue Teva for infringing the '425 and '587 patents, the FDA will be able to approve Teva's generic version of risperidone oral solution upon the expiration of the '663 patent. Teva will be able to commercially market its generic product immediately upon receiving FDA approval.

Apotex subsequently submitted an ANDA application to the FDA seeking approval to market its generic version of risperidone oral solution, in which Apotex also filed Paragraph IV Certifications on the '425 and '587 patents. In January 2006, Apotex amended its ANDA and provided Janssen with an additional Paragraph IV Certification directed to the '663 patent. On March 3, 2006, Janssen sued Apotex for infringing the '663 patent in the United States District Court for the District of New Jersey, but Janssen did not sue Apotex on the '425 and '587 patents (collectively, the unasserted patents). In its Answer to Janssen's Complaint on April 25, 2006, Apotex asserted four counterclaims, including claims for declaratory judgment of noninfringement of the two unasserted patents. Specifically, Apotex sought a declaratory judgment of noninfringement with respect to the two unasserted patents under the Declaratory Judgment Act, 28 U.S.C. § 2201, and the MMA to the Hatch-Waxman Act, 21 U.S.C. § 355(j)(5)(C) and 35 U.S.C. §



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271(e)(5).<sup>4</sup> On June 28, 2006, Janssen moved to dismiss these two counterclaims on the ground that the action did not present a case or controversy as required by Article III of the Constitution.

On December 8, 2006, Janssen provided Apotex with a covenant-not-to-sue with respect to the '425 and '587 patents. After granting the covenant, Janssen requested that Apotex withdraw its counterclaims. Apotex refused. On October 11, 2007, the district court granted Janssen's motion to dismiss Apotex's counterclaims for lack of subject matter jurisdiction. The district court found "no case or controversy" regarding the '425 and '527 patents. This appeal followed.

## DISCUSSION

Whether an "actual controversy" exists that is sufficient to sustain federal subject matter jurisdiction is a question of law this court reviews *de novo*. *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1335-36 (Fed.Cir.2007). In the ANDA context, Congress extended federal court jurisdiction under the Declaratory Judgment Act, 28 U.S.C. § 2201, to ANDA Paragraph IV disputes, 21 U.S.C. § 355(j)(5)(C). Congress also directed federal courts to exercise jurisdiction over these ANDA Paragraph IV declaratory

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4. Because Apotex's counterclaims on the '425 and '587 patents were pending "on or after" the enactment of the MMA (December 8, 2003), Apotex can rely upon the declaratory judgment provision of that legislation. See MMA § 1101(c)(1).

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judgment actions "to the extent consistent with the Constitution," 35 U.S.C. § 271(e)(5). The relevant text of the Declaratory Judgment Act reads:

In a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.

28 U.S.C. § 2201(a). The Declaratory Judgment Act's "actual controversy" requirement "refers to the type of 'Cases' and 'Controversies' that are justiciable under Article III." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 S.Ct. 764, 771, 166 L.Ed.2d 604 (2007).

In *MedImmune*, the Supreme Court stated that a justiciable declaratory judgment action exists when:

the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

*Id.* at 771 (citation omitted). The Court emphasized that the dispute must be:

"definite and concrete, touching the legal relations of parties having adverse legal

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interests;" and that it be "real and substantial" and "admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts."

*Id.*

Apotex argues that it is suffering three actual and continuing injuries which create a substantial controversy of sufficient immediacy to warrant the issuance of a declaratory judgment. Specifically, Apotex argues that (1) it is unable to promptly launch its generic risperidone product and compete in the market immediately upon the expiration of the '663 patent; (2) its approval of its noninfringing generic risperidone product is being indefinitely delayed; and (3) its affiliates, suppliers, and downstream customers face patent uncertainty because Janssen's covenant-not-to-sue does not cover them. We address each alleged injury in turn.

### **A. Prompt Launch**

Apotex argues that absent a declaratory judgment with respect to the '425 and '587 patents and regardless of Janssen's grant of a covenant-not-to-sue, it continues to suffer a cognizable harm of being unable to launch its generic risperidone product immediately upon the expiration of the '663 patent. Apotex contends that this injury creates a substantial controversy of sufficient

*Appendix A*

immediacy to warrant the issuance of a declaratory judgment. Without a declaratory judgment, Teva's 180-day exclusivity period will commence when it commercially launches its generic risperidone product after the expiration of the '663 patent. Therefore, the earliest Apotex will be able to enter the market is 181 days after the expiration of the '663 patent. However, if Apotex is successful on its declaratory judgment action, Teva's 180-day exclusivity period will be triggered at a time that Teva will be unable to launch its generic product. If Teva's 180-day exclusivity period is exhausted prior to the expiration of the '663 patent, Apotex will be able to enter the market immediately upon the expiration of the '663 patent.<sup>5</sup>

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5. As Teva was the first Paragraph IV ANDA filer with respect to the '425 and '587 patents, it is entitled to a 180-day exclusivity period. Teva's 180-day exclusivity period can be triggered by one of two events: (1) Teva's commercial launch of its product; or (2) a favorable court judgment with respect to both the '425 and '587 patents. Because Teva filed a Paragraph III Certification for the '663 patent, the FDA cannot approve Teva's ANDA until the '663 patent expires. As Teva cannot launch prior to FDA approval, the earliest Teva can market its generic product is at the expiration of the '663 patent. Moreover, because Teva failed to obtain a favorable court judgment with respect to the '425 and '587 patents, Teva will only be able to trigger its 180-day exclusivity period by commercially launching its generic product. A subsequent Paragraph IV ANDA filer can trigger Teva's 180-day exclusivity period by obtaining a court judgment that both the '425 and '587 patents are invalid or noninfringing. Therefore, if Apotex obtains a favorable court judgment on the '425 and '587 patents, Teva's 180-day

(Cont'd)

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Apotex contends that *Caraco Pharm. Labs. v. Forest Labs.*, 527 F.3d 1278 (Fed.Cir.2008), in which this court held that despite the existence of a covenant-not-to-sue, a declaratory judgment claim brought under the Hatch-Waxman Act presents a justiciable Article III controversy, is controlling. We disagree.

Jurisdiction over a declaratory judgment action must be present “at all stages of review, not merely at the time the complaint is filed.” *Steffel v. Thompson*, 415 U.S. 452, 459 n. 10, 94 S.Ct. 1209, 39 L.Ed.2d 505 (1974); see *Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1344 (Fed.Cir.2007) (“The burden is on the party claiming declaratory judgment jurisdiction to establish that such jurisdiction existed at the time the claim for declaratory relief was filed and that it has continued since.”); *Int’l Med. Prosthetics Research Assocs., Inc. v. Gore Enter. Holdings, Inc.*, 787 F.2d 572, 575 (Fed.Cir.1986) (“[J]urisdiction over [ ] a declaratory judgment action [must have] existed at, and has continued since, the time the complaint was filed.”). We agree with the parties that if Apotex had not stipulated to the validity of the ‘663 patent, then *Caraco* would have been controlling. However, Apotex stipulated to the validity, infringement, and enforceability of the ‘663 patent on May 11, 2007. Therefore, while the harm that

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(Cont’d)

exclusivity period will begin immediately-regardless of whether the ‘663 patent has expired. This would result in Teva’s 180-day exclusivity period beginning during a time when it cannot secure FDA approval and therefore cannot launch its product.

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created a justiciable Article III controversy in *Caraco* was present when Apotex filed its counterclaims on April 25, 2006, that harm ceased to exist upon Apotex's stipulation. As such, the harm that gave rise to jurisdiction over the declaratory judgment claims in *Caraco* was no longer present on October 11, 2007—the date the district court dismissed the instant case. Further, we conclude that the harm that has continuously existed in the present case—Apotex's inability to launch its generic product immediately upon the expiration of the '663 patent—is not sufficient to give rise to declaratory judgment jurisdiction.

In *Caraco*, Forest Laboratories Inc., et al. (Forest) was the pioneer pharmaceutical company, Ivax Pharmaceuticals, Inc. (Ivax) was the first Paragraph IV ANDA filer, and Caraco Pharmaceutical Laboratories, Ltd. (Caraco) was the subsequent Paragraph IV ANDA filer. 527 F.3d at 1286, 1288. Forest listed two patents in the Orange Book in relation to its NDA. *Id.* at 1286. Both Ivax and Caraco filed Paragraph IV ANDAs with respect to both of the listed patents. *Id.* at 1286, 1288. Forest chose to sue Ivax on only one of the two listed patents. *Id.* at 1286. Forest's patent was found valid, infringed, and enforceable. *Id.* (citing *Forest Labs., Inc. v. Ivax Pharms., Inc.*, 501 F.3d 1263 (Fed.Cir.2007)). After Caraco filed its Paragraph IV ANDA, Forest sued Caraco on only the previously litigated patent and granted a covenant-not-to-sue on the unlitigated, unasserted patent. *Id.* at 1288. Caraco brought a declaratory judgment action for noninfringement of the unlitigated, unasserted patent. *Id.* Caraco wanted to be



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able to challenge both patents and if successful, this would trigger Ivax's 180-day exclusivity period *at a time when Ivax could obtain FDA approval and then launch its product*. Hence, if Caraco was successful, Ivax would get its 180-day exclusivity period sooner and Caraco would be able to obtain FDA approval earlier—resulting in greater competition at an earlier time. Without a declaratory judgment, Caraco could be excluded from selling a noninfringing product even if the asserted patent was proven to be invalid. *See id.* at 1287, 1296 n.14. Therefore, Caraco could have been blocked from entering the market by an invalid patent. *Id.*

The key difference between *Caraco* and this case is that the harm that gave rise to the jurisdiction over the declaratory judgment claim in *Caraco* ceased to exist once Apotex stipulated to the validity, infringement, and enforceability of the '663 patent. Therefore, unlike *Caraco*, Apotex cannot claim that at the time of the district court's dismissal it was being excluded from selling a noninfringing product by an invalid patent—it stipulated to the validity of the '663 patent. Even if Apotex successfully invalidates the '425 and '527 patents, it cannot obtain FDA approval until the expiration of the '663 patent because of its stipulations with respect to that patent. Instead, the harm to Apotex that has continuously existed is its exclusion from selling its alleged noninfringing product *during* Teva's statutorily entitled 180-day exclusivity period. Apotex is being excluded from the market by Teva's 180-day exclusivity period—a period which Teva is entitled to under the Hatch-Waxman Act. This is a different injury than that alleged in *Caraco*.



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Apotex's inability to promptly launch its generic risperidone product because of Teva's 180-day exclusivity period is not a cognizable Article III controversy, but a result envisioned by the Hatch-Waxman Act. As noted above, the Hatch-Waxman Act struck a careful balance between encouraging the development of new drugs and enabling the marketing of low-cost generic drugs. See *Andrx Pharms.*, 276 F.3d at 1371. To this end, Congress decided to give generic pharmaceutical companies a 180-day exclusivity period as an incentive to challenge suspect Orange Book listed patents. The 180-day exclusivity period is important to generic pharmaceutical companies as it promotes patent challenges by enabling a generic company a period to recover its investment in these challenges. See C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L.Rev. 1553, 1605 (2006) (noting the importance of the 180-day exclusivity period for decreasing the free-rider problem and concomitantly incentivizing challenges of Orange Book listed patents); see also *Purepac Pharm. Co. v. TorPharm, Inc.*, 354 F.3d 877, 879 (D.C.Cir.2004) ("In order to encourage paragraph IV challenges, thereby increasing the availability of low-cost generic drugs . . . [the first Paragraph IV ANDA filer] has the right to sell its drug without competition [from other generic entrants] for 180 days."). As the import of the 180-day exclusivity period is clear, we hold that Apotex's exclusion from the market because of Teva's entitlement to this statutory exclusionary period does not present a justiciable Article III controversy.

*Appendix A***B. Indefinite Delay**

Second, Apotex argues that absent a declaratory judgment action, its approval of its noninfringing generic risperidone product will be indefinitely delayed until Teva's 180-day exclusivity period is triggered. Apotex contends that Teva does not have to commercially launch immediately after the expiration of the '663 patent, and that Teva may indefinitely delay launching for various reasons (i.e., substantive problems with its applications which may prevent FDA approval; stock-piling drug product; or concerns over brand patents).<sup>6</sup>

Apotex filed its counterclaims seeking declaratory judgment of noninfringement of the '425 and '587 patents on April 25, 2006. At this time, Teva could not launch its generic product for at least another two years.<sup>7</sup> The district court dismissed the counterclaims on October 11, 2007 more than six months before Teva could have launched. Final judgment was entered on November 2, 2007. At the time of the final judgment dismissing the counterclaims, the harm alleged by Apotex was too speculative because Teva could not yet have launched. We heard oral arguments in this case on July 7, 2008, approximately a week after Teva could have

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6. In 2003, Congress eliminated the possibility that the first Paragraph IV ANDA filer may indefinitely delay launching its generic product. *See supra* note 2.

7. The earliest Teva could have launched its generic product was on June 29, 2008—the expiration of the '663 patent pediatric exclusivity period.

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launched its generic product.<sup>8</sup> However, we are not deciding whether the facts alleged on July 7, 2008—the date we heard oral arguments—give rise to a justiciable Article III case or controversy.<sup>9</sup> We hold that at the time

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8. At the time we heard oral argument, both parties agreed that Teva had not yet launched its generic risperidone oral solution.

9. Jurisdiction over a declaratory judgment action must be present “at all stages of review, not merely at the time the complaint is filed.” *Steffel*, 415 U.S. at 459 n. 10, 94 S.Ct. 1209. As noted above, the court was divested of jurisdiction on May 11, 2007 the date that Apotex’s stipulated to the validity, enforceability, and infringement of the ‘663 patent. In limited circumstances, temporary jurisdictional defects—defects that arise after the filing date of the complaint—may be cured before the district court enters final judgment. *See Mars, Inc. v. Coin Acceptors, Inc.*, 527 F.3d 1359, 1370 (Fed.Cir.2008) (holding that patentee must reacquire title to a patent prior to final judgment to correct the jurisdictional defect that arises when the plaintiff loses title to the patent during litigation); *Schreiber Foods, Inc. v. Beatrice Cheese, Inc.*, 402 F.3d 1198, 1203 (Fed.Cir.2005) (“In circumstances where dismissal for lack of initial standing is not required, the Supreme Court held in *Caterpillar [Inc. v. Lewis]*, 519 U.S. 61, 117 S.Ct. 467, 136 L.Ed.2d 437 (1996),] that jurisdictional defects can be cured before judgment.”); *Insituform Tech., Inc. v. CAT Contracting, Inc.*, 385 F.3d 1360, 1371-72 (Fed.Cir.2004) (holding that temporary loss of jurisdiction during patent litigation can be cured before final judgment). As Apotex failed to cure the jurisdictional defect by the time the district court entered final judgment, we need not reach the issue of whether this case constitutes one of the limited circumstances in which temporary jurisdictional defects can be cured.

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when the district court entered final judgment in this case, Apotex's alleged harm of indefinite delay of approval was too speculative to create an actual controversy to warrant the issuance of a declaratory judgment.

At no time between the filing of the counterclaims through the final judgment was there any basis to conclude that Teva will, or is likely to, delay in bringing its generic product to market in the future. In *Caraco*, this court considered the same harm that Apotex alleges and concluded that it was insufficient to create a justiciable Article III case or controversy. *See Caraco*, 527 F.3d at 1296 n. 14 (noting possible delay of the first Paragraph IV ANDA filer launching after the expiration of a patent is too speculative to create a justiciable Article III case or controversy). Our decision in *Caraco* is supported by Supreme Court precedent which has emphasized that the dispute must be "definite and concrete" and be "real and substantial" in order to give rise to justiciable Article III case or controversy. *MedImmune*, 127 S.Ct. at 771; *see Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1339 (Fed.Cir.2008) (noting *MedImmune* "did not change the bedrock rule that a case or controversy must be based on a *real and immediate* injury . . . an objective standard that cannot be met by a purely subjective or speculative fear of future harm"). Therefore, we hold that a possible delay in the future of a first Paragraph IV ANDA filer in launching its generic product does not give rise to declaratory judgment jurisdiction.

*Appendix A***C. Covenant-Not-to-Sue**

Finally, Apotex argues that Janssen's covenant-not-to-sue is deficient as it does not protect Apotex's affiliates, suppliers, and downstream customers. We disagree. The relevant portion of Janssen's covenant-not-to-sue states:

Janssen unconditionally covenants not to sue or otherwise seek to hold Apotex liable based on its manufacture, having manufactured, importation, distribution, use, sale and/or offering for sale of the risperdal oral solution, 1 mg/ml that are described in and the subject of Abbreviated New Drug Application No. 77-719, as filed and as provided to counsel for Janssen on or about July 13 and 25, 2006 ("the ANDA"), for infringement of United States Patents Nos. 5,453,425 ("the '425 patent") [and] 5,616,587 ("the '587 patent"). . . . Similarly, Janssen would not sue or otherwise seek to hold Apotex's customers or distributors liable based upon the importation, distribution, use, sale and/or offering for sale of the risperdal oral solution, 1 mg/ml that are described in and the subject of the ANDA for infringement of the '425 patent [and] the '587 patent. . . .

The covenant expressly gives Apotex protection from suit for "manufacture [and/or] having manufactured" the claimed product. The "having manufactured" language

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expressly covers all suppliers and affiliates involved in the manufacturing process. *See Cyrix Corp. v. Intel Corp.*, 77 F.3d 1381, 1388 (Fed.Cir.1996) ("ST acted within the scope of its 'have made' right under the ST-Intel agreement when it had ST-Italy make the microprocessors and then sold them to Cyrix."). Similarly, the covenant protects all of Apotex's customers without any distinction between direct and downstream customers as it states "[s]imilarly, Janssen would not sue or otherwise seek to hold Apotex's customers and distributors liable. . . ." Therefore, we hold Janssen's covenant-not-to-sue is not deficient, as it protects Apotex's affiliates, suppliers and downstream customers.

**CONCLUSION**

As we conclude no jurisdiction existed for Apotex's declaratory judgment action, we need not address the remainder of the parties' arguments. For the foregoing \*1364 reasons, we affirm the district court's dismissal of Apotex's declaratory judgment action.

**AFFIRMED**



**APPENDIX B — OPINION OF THE UNITED  
STATES DISTRICT COURT FOR THE DISTRICT  
OF NEW JERSEY FILED OCTOBER 11, 2007**

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

**Hon. Dennis M. Cavanaugh**

Civil Action No. 06-cv-1020(DMC)

**JANSSEN PHARMACEUTICA, N.V. and  
JANSSEN PHARMACEUTICA PRODUCTS,**

**Plaintiffs,**

**v.**

**APOTEX, INC.,**

**Defendant.**

**OPINION**

**DENNIS M. CAVANAUGH, U.S.D.J.:**

This matter comes before the Court upon Plaintiffs Janssen Pharmaceutica, N.V. and Janssen Pharmaceutica Products, L.P.'s (Plaintiffs) motion to dismiss Defendant Apotex's Counterclaims III and IV regarding U.S. Patent Numbers 5,453,425 (the '425 patent) and 5,616,587 (the '587 patent) pursuant to Fed.R.Civ.P. 12(b)(1) and Defendant Apotex's motion for



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summary judgment seeking a declaratory judgment of non-infringement of the '425 patent and the '587 patent pursuant to Fed.R.Civ.P. 56 and L.Civ.R. 56.1. Pursuant to Rule 78 of the Federal Rules of Civil Procedure, no oral argument was heard. After carefully considering the submissions of the parties, and based on the following, this Court finds that Plaintiffs' motion to dismiss Defendant's Counterclaims III and IV is **granted**. As such, Defendant's motion for summary judgment is moot.

**I. Background<sup>1</sup>**

Plaintiffs are the patent owners for various forms of risperidone. Specifically, Plaintiffs own "Risperidone Oral Formulation", which is the '425 patent and "Aqueous Risperidone Formulations", which is the '587 patent. Apotex is a manufacturer of various products, including the generic versions of Plaintiffs' '425 and '587 patents, which it has researched and prepared for market. On or about March 3, 2006, Plaintiffs filed suit against Defendant, and other entities alleging patent infringement of U.S. Patent No. 4,804,663 (the '663 patent) for risperidone oral solution. On or about April 26, 2006, Defendant filed an answer and counterclaims, among other claims, seeking declaratory judgments of non-infringement of the '425 and '587 patents. Defendant agreed to be bound by a final, unappealable decision in the actions brought against the other entities

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1. The facts set forth in this Opinion are taken from the undisputed facts in each party's moving papers.

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regarding the '663 patent. On October 2, 2007, this Court entered a Judgment in favor of Plaintiffs and against Defendant with respect to the infringement claims of the '663 patent.

On June 28, 2006, Plaintiffs filed the present motion to dismiss Defendant's Counterclaims III and IV, pertaining to patents '425 and '587. On January 30, 2007, Defendant filed the present motion for summary judgment for non-infringement of patents '425 and '587. On February 21, 2007, Judge Lifland Ordered a Stay of the summary judgment motion until this Court decided the motion to dismiss.

Plaintiffs move to dismiss Defendant's Counterclaims III and IV pursuant to Fed.R.Civ.P. 12(b)(1) for lack of subject matter jurisdiction. Counterclaims III and IV seek declaratory judgment of non-infringement of patents '425 and '587 as Defendant alleges without Janssen's approval, it would be unable to market the competing generic drugs.

Plaintiffs listed the '663, '425 and '587 patents in the United States Food and Drug Administration's "Orange Book" in connection with Plaintiffs' New Drug Application (NDA) for risperidone. The '663 patent covers the compound risperidone and the '425 and '587 patents cover aqueous solutions for risperidone and methods for preparing these solutions; thus, the '425 and '587 patents require more than simply risperidone.

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Prior to September 16, 2005, Defendant submitted an abbreviated new drug application (ANDA) seeking to engage in the commercial manufacture of the generic version of risperidone oral solution. On September 16, 2005, Defendant sent Plaintiff a Paragraph IV Certification for the '425 and '587 patents. On January 26, 2006, Defendant amended its ANDA to assert a Paragraph IV Certification against the '663 patent. Plaintiff acted within 45 days of receiving the additional Paragraph IV Certification and brought a patent infringement suit regarding the '663 patent **only**. As shown above, this patent infringement is no longer in issue. In its Answer to Plaintiffs' Complaint, Defendant counterclaims alleging non-infringement of the '425 and '587 patents and seeks declaratory judgment from this Court holding that Defendant has not infringed patents '425 or '587.

On December 8, 2006, Plaintiffs provided Defendant with a covenant not to sue for infringement of the '425 and '587 patents. This covenant not to sue protects Defendant and Defendant's customers and distributors. While there may have been a case or controversy prior to Plaintiffs providing the covenant not to sue, no case or controversy exists regarding the '425 and '587 patents, as a result of the covenant not to sue. As such, this Court finds that Plaintiffs' motion to dismiss Defendant's Counterclaims III and IV, pertaining to the '425 and '587 patents is **granted** and Defendant's motion for summary judgment is moot.

*Appendix B***II. Standard of Review****MOTION TO DISMISS PURSUANT TO RULE 12(b)(1)**

Upon a Rule 12(b)(1) motion addressing the existence of subject matter jurisdiction over a plaintiff's complaint, "no presumptive truthfulness attaches to a plaintiff's allegations." *Martinez v. U.S. Post Office*, 875 F. Supp. 1067, 1070 (D.N.J.1995) (citing *Mortensen v. First Fed. Sav. and Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977)). "Accordingly, unlike a Rule 12(b)(6) motion, consideration of a Rule 12(b)(1) jurisdiction-type motion need not be limited; conflicting written and oral evidence may be considered and a court may 'decide for itself the factual issues which determine jurisdiction.'" *Id.* (citing *Williamson v. Tucker*, 645 F.2d 404, 413 (5th Cir.) *cert. denied*, 454 U.S. 897 (1981)). "When resolving a factual challenge, the court may consult materials outside the pleadings, and the burden of proving jurisdiction rests with the plaintiff." *Med. Soc'y of N.J. v. Herr*, 191 F. Supp. 2d 574, 578 (D.N.J. 2002) (citing *Gould Elecs. Inc. v. U.S.*, 220 F.3d 169, 176, 178 (3d Cir. 2000)). However, "[w]here an attack on jurisdiction implicates the merits of plaintiff's [F]ederal cause of action, the district court's role in judging the facts may be more limited." *Martinez*, 875 F. Supp. at 1071 (citing *Williamson*, 645 F.2d at 413 n.6).

**III. Discussion**

After carefully reviewing the record and papers submitted by all parties, and based on the following, this

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Court finds that Plaintiffs' motion to dismiss Defendant's counterclaims III and IV is **granted** because there is no case or controversy surrounding the patents Defendant alleges are in issue.

At the time Plaintiffs filed their motion to dismiss, *Teva Pharms. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324 (Fed. Cir. 2005) was controlling law, which applied a two part test to determine whether there was a case or controversy. The two-part test required both an explicit threat or other action by the patentee which creates a reasonable apprehension of suit and present activity which would constitute infringement. *Id.* at 1332.

*MedImmune, Inc. v. Genetech, Inc.*, 127 U.S. 764 (2007) is now controlling law to determine whether a justiciable declaratory judgment action exists. "Whether the facts alleged, under all the circumstances show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Id.* at 768. This Court, after considering the totality of the circumstances, finds that no substantial controversy exists and Plaintiffs' motion to dismiss Defendant's Counterclaims III and IV is granted.

Defendant asserts that *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals*, 482 F.3d 1330 establishes that *MedImmune* is entirely applicable to the facts in this case, and thus mandates that subject matter jurisdiction exists in this declaratory judgment

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action. However, the present action is distinguished from *Novartis* as Plaintiffs point out, there was no covenant not to sue in *Novartis*. *Novartis* at 1332.

In reaching its decision in *Novartis*, the Circuit reviewed the legislative history of the declaratory judgment provision of the Hatch-Waxman Act<sup>2</sup> and held that a covenant not to sue usurps the opportunity to bring an action for declaratory judgment.

We believe that the only circumstance in which a case or controversy might not exist would arise in the rare circumstance in which the patent owner and brand drug company have given the generic applicant a covenant not to sue, or otherwise formally acknowledge that the generic applicant's drug does not infringe.

*Novartis* at 1338. In this case, a covenant not to sue was given to Defendant on December 8, 2006. Further, in *Merck & Co. v. Apotex*, (06-230), The United States District Court for the District of Delaware issued an Order on April 10, 2007 granting Merck's motion to dismiss for lack of subject matter jurisdiction because of Merck's covenant not to sue.

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2. The Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. §§355, 360cc and 35 U.S.C. §§156, 271, 282 is commonly known as The Hatch-Waxman Act. The Act requires an innovator pharmaceutical company that seeks to manufacture a new brand drug to file a New Drug Application with the Federal Food and Drug Administration.



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The same situation arises here. Plaintiffs gave Defendant a covenant not to sue, and therefore Plaintiffs' motion to dismiss regarding the patents in the covenant not to sue must be granted.

**IV. Conclusion**

Based on the foregoing facts and law, it is clear that there is no case or controversy regarding patents '425 and '587, and as such, this Court does not have subject matter jurisdiction and must dismiss Defendant's counterclaims III and IV. Plaintiffs' motion to dismiss Defendant's Counterclaims III and IV is granted and Defendant's motion for summary judgment seeking declaratory relief regarding patents '425 and '587 is moot. An appropriate Order accompanies this Opinion.

S/ Dennis M. Cavanaugh  
Dennis M. Cavanaugh, U.S.D.J.

Date: October 11 , 2007



**APPENDIX C — ORDER OF THE UNITED STATES  
COURT OF APPEALS FOR THE FEDERAL  
CIRCUIT DENYING PETITION FOR REHEARING  
FILED OCTOBER 29, 2008**

**UNITED STATES COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT**

2008-1062

**JANSSEN PHARMACEUTICA, N.V. and  
JANSSEN PHARMACEUTICA PRODUCTS, L.P.,**

**Plaintiffs-Appellees,**

**v.**

**APOTEX, INC.,**

**Defendant-Appellant.**

Appeal from the United States District Court for the  
District of New Jersey in case no. 06-CV-1020, Judge  
Dennis M. Cavanaugh.

**ORDER**

A combined petition for panel rehearing and for  
rehearing en banc having been filed by the Appellant,  
and a response thereto having been invited by the court  
and filed by the Appellees, and the petition for rehearing  
and response, having been referred to the panel that  
heard the appeal, and thereafter the petition for

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rehearing en banc and response having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on November 5, 2008.

FOR THE COURT,

s/ Jan Horbaly  
Clerk

Dated: 10/29/2008

**APPENDIX D — U.S. CONST., ART. III, § 2**  
**CONSTITUTION OF THE UNITED STATES**

**ARTICLE III**

**Section 2.** The judicial Power shall extend to all Cases, in Law and Equity, arising under this Constitution, the Laws of the United States, and Treaties made, or which shall be made, under their Authority;—to all Cases affecting Ambassadors, other public Ministers and Consuls;—to all Cases of admiralty and maritime Jurisdiction;—to Controversies to which the United States shall be a Party;—to Controversies between two or more States;—between a State and Citizens of another State;—between Citizens of different States;—between Citizens of the same State claiming Lands under Grants of different States, and between a State, or the Citizens thereof, and foreign States, Citizens or Subjects.

**APPENDIX E – 21 U.S.C.A. § 355(j)(5)(C)  
(West Supp. 2005)**

**TITLE 21 – FOOD AND DRUGS**

**CHAPTER 9 – FEDERAL FOOD, DRUG, AND  
COSMETIC ACT**

**SUBCHAPTER V – DRUGS AND DEVICES**

**PART A – DRUGS AND DEVICES**

**§ 355. New drugs**

\* \* \*

**(j) Abbreviated new drug applications**

\* \* \*

**(5) \* \* \***

**(C) CIVIL ACTION TO OBTAIN PATENT  
CERTAINTY.—**

**(i) DECLARATORY JUDGMENT ABSENT  
INFRINGEMENT ACTION.—**

**(I) IN GENERAL.—**

No action may be brought under section 2201 of title 28, by an applicant under paragraph (2) for a declaratory judgment with respect to a patent

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which is the subject of the certification referred to in subparagraph (B)(iii) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

**(II) FILING OF CIVIL ACTION.—**

If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of Title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the

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applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

**(III) OFFER OF CONFIDENTIAL ACCESS  
TO APPLICATION.—**

For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of



*Appendix E*

confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

**(ii) COUNTERCLAIM TO INFRINGEMENT ACTION.—**

**(I) IN GENERAL.—**

If an owner of the patent or the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does not claim either—

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(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

**(II) NO INDEPENDENT CAUSE OF ACTION.—**

Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

**(iii) NO DAMAGES.—**

An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

**APPENDIX F – 35 U.S.C.A. § 271(e)(5)  
(West Supp. 2005)**

**TITLE 35 – PATENTS**

**PART III – PATENTS AND PROTECTION OF  
PATENT RIGHTS**

**CHAPTER 28 – INFRINGEMENT OF PATENTS**

**§ 271. Infringement of patent**

\* \* \*

(e) \* \* \*

(5) Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

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(2)

No. 08-959

Supreme Court, U.S.  
FILED  
FEB 17 2009  
OFFICE OF THE CLERK

IN THE  
Supreme Court of the United States

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APOTEX, INC.,

*Petitioner,*

*v.*

JANSSEN PHARMACEUTICA, N.V.  
and JANSSEN, L.P.,

*Respondents.*

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ON PETITION FOR A WRIT OF CERTIORARI TO THE  
UNITED STATES COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT

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SUPPLEMENTAL BRIEF

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February 17, 2009

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**RULE 29.6 CORPORATE  
DISCLOSURE STATEMENT**

Apotex included a Rule 29.6 Corporate Disclosure Statement in its Petition for a Writ of Certiorari filed on January 27, 2009. Pursuant to Rule 29.6 of this Court's Rules, Apotex incorporates by reference that prior Statement.

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## **SUMMARY OF SUPPLEMENTAL SUBMISSION**

Petitioner Apotex respectfully submits this Supplemental Brief, pursuant to Rule 15.8 of this Court's Rules, to briefly advise the Court of new and "intervening matter" that was "not available at the time of [Apotex's] last filing" on January 27, 2009.

### **INTERVENING MATTER PRESENTED TO THE COURT**

In its Petition, filed January 27, 2009, Apotex advised the Court that as of the date of that filing, the first ANDA-filer (Teva) for generic risperidone oral solution was not yet finally approved to market its product, despite having filed its ANDA in 2002 and having been approvable (but not approved) since 2006. As of that date, this fact was accurate. However, Apotex respectfully advises the Court that on or about January 30, 2009, the U.S. Food and Drug Administration ("FDA") granted final approval to Teva to market its generic risperidone oral solution product. On information and belief, Teva commenced selling its generic product on or about that same date. Apotex does not believe that such facts change or otherwise alter any of the arguments in its original Petition.

Apotex anticipates that respondent Janssen may now raise an issue of purported mootness, whether in an opposition brief or by way of motion, in light of FDA's approval and Teva's subsequent launch of its product. However, Apotex fully intends to oppose any such suggestion of mootness and disagrees that the underlying dispute raised in Apotex's Petition is in fact moot. To the contrary, the underlying dispute between Apotex and Janssen remains very much a live controversy of critical importance to Apotex, the generic pharmaceutical industry, and the public that relies upon that industry to bring affordable

medicines to market. Alternatively, this case falls squarely within the “capable of repetition, yet evading review” exception to the mootness doctrine, as demonstrated by discussion already set forth in Apotex’s pending Petition. Apotex reserves its rights to fully respond at an appropriate time and through the appropriate means to any suggestion or claim of mootness asserted by Janssen herein.

### CONCLUSION

The new matter described above should change nothing. Rather, the petition for certiorari should be granted. Alternatively, the Court should call for the views of the Solicitor General before ruling on this Petition.

Respectfully submitted,

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February 17, 2009